



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 7, 2016

G.K. Sangha
Toxicology & Regulatory Affairs Consultant
DAKEM Inc.
303 Celebration Blvd
Celebration, FL, 34747

Subject: Label Amendment – Addition of efficacy claim against mosquitoes that may transmit Zika virus and update of company information
Product Name: MOZZ’CARE Insect Repellent
EPA Registration Number: 88957-1
Application Date: February 24, 2016
Decision Number: 514558

Dear Ms. Sangha:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 88957-1
Decision No. 514558

with FIFRA section 6. If you have any questions, please contact Tim Ciarlo by phone at 703-347-8082, or via email at Ciarlo.Timothy@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. S.', with a long horizontal flourish extending to the right.

Jennifer Urbanski Saunders, Product Manager 4
Invertebrate & Vertebrate Branch 1 (IVB1)
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

MOZZ'CARE Insect Repellent

Long-lasting, 14 hour effective protection from mosquitoes and ticks including mosquitoes that may transmit West Nile Virus, Chikungunya, Dengue and Zika and ticks that may transmit Lyme disease

Repels biting flies, stable flies, black flies, gnats, chiggers, biting midges and sand flies for up to 8 hours.

WATER RESISTANT

ACTIVE INGREDIENT: PICARIDIN, 1-Methylpropyl-2-(2-hydroxyethyl)-1-piperidine carboxylate	20%
OTHER INGREDIENTS	80%
TOTAL	100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

STOP – Read This Entire Label Before Use

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

Causes moderate eye irritation. Avoid contact with eyes. Wash your hands with soap and water after handling, returning indoors, and before eating, drinking and chewing gum, using tobacco or using the toilet.

The information below describes the first aid procedures for incidents involving MOZZ'CARE Insect Repellent Spray:

FIRST AID

IF IN EYES:

- Hold eye open and rinse gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a Poison Control Center or doctor for treatment advice.

IF SWALLOWED:

- Call a physician or poison control center immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a Poison Control Center or a doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-424-9300 for emergency medical information.

IN CASE OF EMERGENCY, CALL: 1-800-424-9300 CCN801214

STORAGE AND DISPOSAL

Store in a cool, dry place out of the reach of children. Container Handling: Non-refillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions or 1-800-526-9377 for disposal instructions. Never place unused product down any indoor or outdoor drain.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read and follow all label directions.

Follow these guidelines when applying MOZZ'CARE Insect Repellent Spray:

Shake well before use. Apply thoroughly to the skin avoiding contact with eyes and mouth. Hold 4 to 6 inches from skin while spraying, keeping nozzle pointed away from face. Slightly moisten skin with a slow sweeping motion. Excessive amounts or frequent reapplication is unnecessary. Do not exceed two applications per day. Apply on face by first spraying small amounts in palms of hands and spreading on face and neck, avoiding your eyes. Do not apply to the hands of small children. When using on children, apply to your hands and then apply it to the child. To apply to a child's face and neck, spray the product into your hands and apply to the child. Take care to avoid mouth and eyes and apply sparingly around ears. Do not allow children to handle the product. Do not spray directly on face. Avoid contact with lips, cuts, wounds, or irritated skin. Do not apply to excessively sunburned skin. Do not apply under clothing. Apply sparingly around ears.

OPTIONAL MARKETING STATEMENTS

[Non-flammable]; [Water based]; [Extreme outdoor]; [Water Resistant]; [Suitable for tropical areas]; [Not oily, greasy or sticky]; [Won't damage plastics and synthetic materials]; [Skin friendly spray]; [For the whole family]; [Can be used on pregnant women]; [Pleasant fresh smell]; [Moisturizes outer layer of skin]; [Pocket size]; [DEET Free]; [Repels mosquitoes for up to 14 hours]; [Repels ticks for up to 14 hours]; [Repels mosquitoes and ticks for up to 14 hours]

EPA Reg. No.: 88957-1
EPA Est. No.: 091948-VA-001
EPA Co. No.: 88957
Net Contents:
Batch No.: See bottom of the bottle

ACCEPTED

Mar 07, 2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 88957-1



DAKEM Inc.
303 Celebration BLVD Celebration, FL 34747
Phone No: 407-960-1882
LABEL TEXT DATE: 02/24/2016